REMARKS

I. Status of the claims

Claims 1-3, 17-19, and 21-22 are pending.

Claim 1 is amended. "Previously presented" amendments are those of the Second Supplemental Amendment filed October 7, 2004.

Claims 4-16, and 20 are withdrawn reserving the right to prosecute them in continuing or divisional applications.

II. Support for the Claim Amendments

page	lines	
3	3-4	"identical" "adjoin one another"
4	Step 8	"peptide regions"
4	Step 9	"contiguous amino acids which are identical to contiguous sequences of the comparative proteins"
	Step 10	"structurally identical peptides"
5	20-21	"sequentially homologous"
6	17-19, 20-28	"immunoassay or immune cell proliferation assays" discussed
9	3-4	"contiguous"
11	31-32	"thus confirming the need to test specific functional utility (immunogenic) of the peptide antigen"

III. An Expert Declaration from Dr. Anderson Showed Why Regenmortel Should be Removed as a Basis for Rejection

A Declaration under 37 C.F.R § 1.132 by Dr. Byron Anderson, an expert in the field of immunology, was appended as Exhibit A in the Response of July 16, 2004. His *Curriculum Vitae* was Exhibit B. As Dr. Anderson testified, mimotopes as reviewed by Regenmortel, "are not proteins or peptide sequences derived from proteins" (Exhibit A, par. 4a) (any homology of a mimotope sequence to a protein sequence is by chance only). Furthermore, Dr. Anderson testifies that the mimotopes of Regenmortel "cannot be defined as a comparative protein as the examiner has

done...." (Exhibit A, par. 4a).

Dr. Anderson testified that the present invention is "unique and inventive," (Exhibit A, par. 4b) and is "a contribution to the field of immunology." (Exhibit A, page 6)

Regenmortel expressly defines his own review as of the:

> Steadily increasing ability to identify antigenic sites in viral proteins and then to design linear peptides that mimic the three-dimensional conformational features of key immunodominant sites in viral proteins.

Note that mimotopes are synthetic peptides designed to mimic a 3-D composition.

> Such molecular libraries often contain peptides that bind to the appropriate antibodies but show no sequence similarity with the viral proteins that the peptides correctly mimic in a functional sense. Such epitopes are called mimotopes because they are thought to mimic discontinuous epitopes of the antigen.
>
> Regenmortel, p. 334.

Regenmortel is limited to "viral proteins."

Also, Claim 1 is amended to clarify that the immunogenic peptides are identical to parts of amino acid sequences of comparative proteins. Claim 1 is not limited to synthetic peptides, which, according to the examiner, is taught in Regenmortel (Action page 2, par. 2). Also, unlike mimotopes, the peptides of the present invention have amino acid sequences that are the same as part of the target protein sequence.

Claim 1 is also amended to clarify that step (f) is not shown in any of the cited publications. All pending claims in the present application relate to claim 1 therefore arguments herein apply to them.

IV. Because Rejections Based on Regenmortel are Faulty, Regenmortel Must be Removed as a Basis for the 103 Rejections

Claims 18-19 were rejected as obvious over Regenmortel and Hasegawa. Claim 22 was rejected as obvious over Regenmortel and Tu.

Because, as shown in Section III herein, and the Declaration Under 1.132 (Appendix A of October 7, 2004 paper) that Regenmortel does not teach the peptides of the present invention, these rejections must fall also.

Hasegawa merely teaches adjuvants. There is no teaching or suggestion to combine Regenmortel and Hasegawa. Even if Regenmortel and Hasegawa were combined, the combination does not render claims 18-19 obvious because neither Regenmortel nor Hasegawa teach or suggest a

plurality of immunogenic peptides that fits the description of claim 1.

On page 5 of the Action, the examiner states that Regenmortel in view of Tu (US Pat 5674483) renders claim 22 obvious. Tu merely teaches a method of administering IL-12 to reduce inflammation. IL-12 is a "heterodimeric cytokine" exceeding the limits of claim 1 (Howard *et al.* Chap. 20, Fundamental Immunology)

In *Nursery Supplies*, the court held:

> One **cannot simply backtrack from the invention to find a connection** to the prior art. Hindsight must be avoided. See *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). Rather, **one must start with the prior art and find some suggestion or motivation either in a single reference** to modify it to produce the claimed invention, or some suggestion or motivation in a group of references to combine them to produce the claimed invention. *Nursery Supplies v. Lerio Corp.*, 45 U.S.P.Q.2d (BNA) 1332 (M.D. Pa. Sept. 19, 1997). (*emphasis added*).

There is no teaching or suggestion to combine Regenmortel and Tu. Even if Regenmortel and Tu were properly combined, the combination does not render claim 22 obvious because Regenmortel does not teach or suggest an immunogenic peptide that fits the description of claim 1, and TU only teaches IL-12.

It is to be noted, however, that citing references which **merely indicate that isolated elements and/or features** recited in the claims are known **is not a sufficient basis** for concluding that the combination of claimed elements would have been obvious. *Ex parte Hiyamizu* (BPAI 1988) 10 PQ. 2d 1393 (*emphasis added*).

Even if all of the elements of a claim are present in the prior art, the claim will not be obvious unless the prior art also contained, at the time the claim was filed, a motivation to combine prior art elements into the claimed invention. The conclusion that the prior art contained a motivation to combine is a conclusion of fact. *Scimed Life Sys. v. Johnson & Johnson*, 2004 U.S. App. LEXIS 510.

Obviousness requires **a suggestion of all limitations** in a claim." *CFMT, Inc. v. Yieldup Int'l Corp.*, 2003 U.S. App. LEXIS 23072 (Fed. Cir. 2003) (*emphasis added*).

To properly combine two references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in either or both of the references, or knowledge generally available to one skilled in the art, which would have led one to combine the relevant teachings of the two references. *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc. et al.* (CAFC 1985) 776 F.

2d 281, 227 USPQ 657; *Ex parte Levengood, supra.* Both the suggestion to make the claimed composition or device or carry out the claimed process and the reasonable expectation of success must be founded in the prior art, not in applicant's disclosure. *In re Vaeck* (CAFC 1991) 947 F. 2d 488, 20 PQ. 2d 1438. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. *In re Shaffer* (CCPA 1956) 229 F. 2d 476, 108 USPQ 326; *In re Skoll* (CCPA 1975) 523 F. 2d 1392, 187 USPQ 481.

In *re Rouffet,* the court held

> "To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court **requires the examiner to show a motivation to combine the references that create the case of obviousness**. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In *re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998). (*emphasis added*).

Therefore, Claims 18-19, and 22 are not obvious over Regenmortel in view of either Hasegawa or Tu.

V. Figures are Illustrative Embodiments and Not Claimed

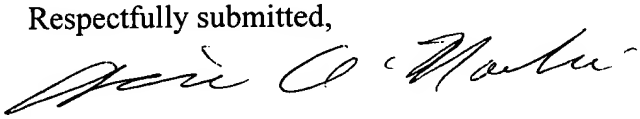
Embodiments in the figures are illustrative of how to apply the steps of claim 1. There are no specific peptides claimed as part of the invention, and case law clearly indicates that claims should not be limited to embodiments.

VI. Conclusion and Summary

In view of the arguments presented herein, please allow all pending claims.

No fees are believed due at this time, however, please charge any additional deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21417/92378).

Respectfully submitted,



Alice O. Martin
Registration No. 35,601

October 29, 2004
Barnes & Thornburg
P.O. Box 2786
Chicago, IL 60690-2786
CHDS01 AOM 205233v2